

K002159

JUN 28 2002

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in compliance with requirements of the Safe Medical Device Act of 1990 and CFR 807.92.

Manufacturer Name

SagaTech Electronics Inc.
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Calgary, Alberta
Canada T2G 3A4
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Contact name: Heather Platt-Melax

Proprietary Name of Device

SnoreSat

Common Name of Device

Ventilatory Effort Recorder

Device Classification

The Anesthesiology Devices Panel has classified devices of this type as class II. Devices of this type have a classification code of MNR, Ventilatory Effort Recorder (21 CFR 868.2375).

Intended Use

The SnoreSat is a device used in the home or hospital, either unattended or attended, that records physiological signals for diagnosis of sleep apnea and detection of periodic limb movement in the adult population. SnoreSat is also used to evaluate efficacy of continuous positive airway pressure (CPAP) in the treatment of sleep apnea.

Device Description

The SnoreSat recorder is a small portable device that is designed to aid in the diagnosis of sleep apnea, measure the efficacy of CPAP therapy, and detect periodic leg movement. SnoreSat has a built in oximeter and an array of sensors to record physiological signals. The signals it records are:

- Blood oxygen saturation, heart rate, pulse amplitude
- Nasal airflow (Through nasal cannula pressure measurement)
- Airflow (Through pneumotachograph when CPAP is used)
- Mask pressure (When CPAP is used)
- Snoring sound
- Body position
- Abdominal movements
- Leg electromyograms (When periododic leg movement is suspected)

SnoreSat is powered using an AC adapter. It has a serial interface for transferring data to a host personal computer for analysis and report generation. Host analysis software is also used to configure the SnoreSat device. Oximetry data is processed using a validated algorithm to generate a respiratory disturbance index (RDI).

Predicate Device Equivalence

There are three predicate devices for the SnoreSat recorder. They are:

1. Oxiflow Digital Recorder Model 9500 from Edentec
2. AutoSet Portable 2 Plus from Resmed
3. Suzanne from Nellcor Puritan Bennett

Performance Testing

Testing was performed to demonstrate that the performance of the SnoreSat in its intended environment was as safe and effective as that of these legally marketed devices.

Functional testing was performed to confirm that the SnoreSat is capable of meeting its stated performance specifications. The SnoreSat passed all tests.

The SnoreSat was tested and found to be compliant with the standards referenced in the "Draft FDA Reviewer Guidance for Premarket Notification", November 1993.

Conclusions

SagaTech Electronics concludes that the SnoreSat recorder meets its stated specifications, operates safely in its intended environment, and is effective in fulfilling its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 2002

SagaTech Electronics, Inc.
c/o Heather Platt-Melax, B.Sc.
3413 8th St., S.E.
Calgary, Alberta
CANADA T2G3A4

Re: K002159
SnoreSat Recorder, Model SS41
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: April 5, 2002
Received: April 15, 2002

Dear Ms. Platt-Melax:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

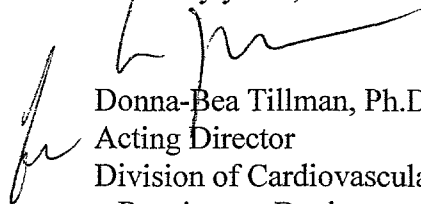
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002159

Device Name: SnoreSat Recorder

Indications For Use: The SnoreSat is a recording device used in the home or hospital, either unattended or attended, that records physiological signals for diagnosis of sleep apnea and detection of periodic limb movement in the adult population. SnoreSat is also used to evaluate efficacy of continuous positive airway pressure (CPAP) in the treatment of sleep apnea.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular
and Respiratory Devices

510(k) Number K002159

(Optional Format 3-10-98)

X

Prescription
use

-or-

Over-the-
counter use